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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Larry Augsburg

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

07/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/749,339

Applicant(s)

AUGSBURGER ET AL.

Examiner

Eric E. Silverman, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 12-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant is advised that the Examiner assigned to this Application has changed. The Examiner currently assigned to this Application is **Eric Silverman, PhD**, whose contact information can be found at the end of this action. Applicant is further advised that this Application is currently assigned to **Art Unit 1615**.

Election/Restrictions

Applicant's election of Group I, claims 1 - 11 in the reply filed on 5/21/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, except for the restriction between groups I - V and XI, the election has been treated as an election without traverse (MPEP § 818.03(a)) for all other groups. With respect to Groups I - V and XI, Applicants' argue out that groups I - V need not be dry, and that Group XI need not have water present. However, Applicants' explanation requires incorporating limitations of the specification into the claims, which is not proper during examination of applications, and thus cannot be considered to be persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1 - 38 are pending. Claims 12 - 38 are withdrawn from consideration, and claims 1 - 11 are treated on the merits in this action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16 – 30 of U.S. Patent No. 5,780,055 to Habib et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because patented claims require a tablet, whereas instant claims 1 – 10 are generic as to the dosage form. Patented claims also do not recite the exact size ranges for cushioning particles as in instant claims, however, copending claim 16 recites a broad range that encompasses all of instant ranges, thus making them obvious. Instant claims are also generic to the nature of the compactable filler and the highly water-absorbing material, whereas patented claims recite specific materials. In this sense, patented claims are a species of instant genus claims, thus rendering instant claims obvious in their entirety.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 3 and 5 – 11 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,780,055 to Habib et al.

Independent claim 1 requires a composition comprising a placebo cushioning component comprising a highly-compactable filler and a highly water-absorbing material, active loaded particles wherein the two components are in a mixture and the mixture is freeze-dried. Note that the claim is understood to be a product by process claim wherein freeze drying is a process step. A substantially dry composition having all of the requisite components will meet the limitations of this claim, even if drying is achieved by another method. Claims 2 and 3 limit the particle sizes, with the ultimate range being from about 20 microns to about 2000 microns. Claims 5 – 7 specify the amount of active loaded particle in the composition, and claims 8 – 10 specify the amount of highly compactable filler in the placebo cushioning component. Claim 11 specifies that the composition is a tablet.

Habib discloses a tablet made from active loaded beads (particles) and cushioning beads (placebo cushioning component). See claim 16, and col. 65 – 66. The placebo cushioning component comprises microcrystalline cellulose (a highly compactable material) and a disintegrant (a highly water absorbing material) in ratios commensurate with instant claims (claim 18). The ratio of active loaded particle to placebo cushioning component is varied, but examples within instantly claimed ranges were prepared (see Table 22, particularly the examples having 25% active particle and 75% cushioning beads, and also the examples having 50% active loaded particles and 50% cushioning beads). The cushioning beads are generally between 0.2 mm (200

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microns) and 2 mm (2,000 microns). See claim 16. At col. 65, beads ranging from 14 – 20 mesh (approximately 1410 – 841 microns – see “Mesh to Micron Conversion Chart” cited on PTO-892). The maximum value of this range is close enough to 1000 microns to read on “about 1000” as recited in instant claim 3. The particles of Habib are freeze-dried (see abstract).

Claims 1 –10 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,254,891 to Anaebonam et al.

The limitations of claims 1 – 3 and 5 – 10 have been discussed previously. Claim 4 further limits the particle size of the cushioning component.

Anaebonam teaches a composition including immediate release drug particles, controlled release drug particles, and placebo particles (cushioning component). See col. 5, line 55 – col. 6, line 63). The placebo particles are made from ethylcellulose, sugar spheres, and methylcellulose in ratios commensurate with instant claims (the cellulosic components being the compressible material and the sugar being the water-absorbing material). See col. 6, lines 64 – 67, and col. 9, lines 21 – 49. The particles are dried in an oven (col. 9, line 21 – 49), which reads on the freeze drying process step (*vide supra*). The cushioning component has a particle size of between 30 and 35 mesh, or 500 – 595 microns (see Mesh to Micron Conversion Chart on PTO-892). The ratio of active loaded particles to cushioning component (claim 2) is also commensurate with instant claims.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,780,055 to Habib et al.

The limitations of claim 3 were discussed previously. Claim 4 further limits the particle size of the cushioning component.

Note that with respect to claim 3, this rejection is based on a different interpretation of the size of the cushioning particles in Habib. Specifically, while it is believed that the size range specified at col. 65 of Habib is sufficient to anticipate claim 3 if it is not sufficient for anticipation, Habib still renders this claim obvious.

The teachings of Habib are discussed above.

Habib does not teach the size ranges of instant claims.

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Importantly, the broad size range taught by Habib encompasses all of the size ranges of instant claims.

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to make particles with the size range of instant claims. When the general conditions for an invention are known, finding the optimal or workable embodiment is not sufficient to impart patentability. See MPEP 2144. In this case, Habib teaches that particles of instant size ranges are suitable for the invention. Finding optimal sizes within the range of Habib is obvious.

Conclusion

No claims are allowed.


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,126,967 contains teachings that are similar to US 6,254,891.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1615


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